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**Item No.: 6029**

December 22, 1998 DRAFT

# THE AGENCY'S RESPONSE TO COMMENT ON THE DRAFT RESIDENTIAL STANDARD OPERATING PROCEDURES (SOPs)

**Comment Topic**: Are the SOPs Representative of All Significant Exposure Scenarios?

**Agency Response**:

The Scientific Advisory Panel (SAP) thought the scenarios were appropriate and had no additions to suggest. The SOP workgroup, however, is now contemplating adding a scenario for bystander exposure (spray drift) from pesticide applications, as well as adding scenarios specific to other "non-home" sites, such as schools, playgrounds, parks, etc. We agree with the SAP that the scenarios require expansion and more clarification regarding other sites as well, such as neighborhood pools, and will address this in the June version.

The SAP also commented that the document should address "reasonable misuse" of pesticide products. While it is not routine for the Agency to regulate on "reasonable misuse" of pesticides, the Agency will investigate on a case-by-case basis when there is epidemiological, poisoning incident, or other information to identify specific problems. Specific to the SOPs, when there are exposure data available indicating that higher than recommended label rates may have been used (e.g., indoor foggers), we will look at the data relative to the impact on the exposure values generated by the SOPs.

Further, the SAP commented that little guidance is provided to estimate exposure across media. The workgroup agrees and will address media differences, such as transferable residues from carpeted floors and different hard surfaces, such as wooden or vinyl floors, to the extent existing data permit.

The SAP wants more details on specific computer models cited in the SOPs. While the Agency did present them briefly at the September, 1997 meeting, we will provide them ahead of time for the next presentation in July, 1999. Along with this comment, the SAP wants the Agency to provide additional guidance regarding the distribution of pesticide contamination across space and time within the residential environment, such as room-to-room variance and estimates of chemical persistence. The indoor air models currently cited in the SOPs do take into consideration these issues, but we will add clarification to the document and, more importantly, look at existing chemical data as part of a "reality" check and for further validation of the models, as well as their

appropriateness as an assessment tool.

The SAP wants clarification as to whether the purpose and use of the SOPs are as a screening tool or to be used in more refined assessments of exposure and risk. The Agency will clarify this as necessary for reviewers. The SOPs are being used both as a screening tool and for more refined assessments, in the absence of chemical-specific data and information to refine our assumptions, exposure and risk estimates.

**Comment Topic**: Is the SOP Document Explicit Enough in Explaining the Source and Rationale for Suggesting Default Assumptions to Be Used in the Absence of Credible Data?

**Agency Response**:

The SAP would like more explanation of the rationale and justification where possible for the assumptions given. Specifically, the SAP is looking for more information on distributions of contamination and intake, the use of summary statistics, the effects of combining numerous conservative assumptions and compounding conservatism and recommends the use of probabilistic methods where data are available. The Agency agrees and will address this issue for each of the individual exposure scenarios as much as possible given the limited data. The Agency also will add available distributional data for the references cited (e.g., Exposure Factors Handbook), as appropriate. Future updates to the SOPs will also include the available residential handler exposure distributions once the Pesticide Exposure Handlers Database (PHED) Version 2.0 is completed. The Agency agrees that the problem of compounding conservatism may be avoided or, at least, minimized, using probabilistic methods. The SOPs will default to methods such as Monte-Carlo analysis, if sufficient data and information of appropriate quality are available to accomplish this. OPP has another workgroup looking at probabilistic assessment methods at this time. The SOP workgroup will be coordinating with them. A related comment by the SAP asks when will data be of sufficient quality to justify their use in exposure assessment, as opposed to relying upon default assumptions. The EPA Exposure Monitoring Guidelines, Series 875, Group A (Applicator) and Group B (Post-application) give guidance on requirements for conducting and submitting acceptable exposure monitoring and residue dissipation studies.

The SAP would like to see additional documentation supporting the choice of exposure scenarios, models, data sets, and default assumptions to be used in the absence of adequate data (e.g., each equation should be supported by current and credible scientific literature). The next version of the SOP's will add new references, as appropriate, including unpublished data references, as available, from current researchers in the area of residential exposure (e.g., activity and hand-to-mouth behavior).

**Comment Topic**: Are the Example Calculations Provided in the SOP Document Clear and

Helpful?

**Agency Response**:

The panel commented that the example calculations are very useful, but could be expanded to demonstrate the difficulty of estimating exposure when data quality varies among components of exposure equations. They commented that example calculations might be developed to demonstrate probabilistic methods and to consider the sensitivity of exposure estimates to spatial and temporal variance in contamination or behavioral variance. The Agency agrees and will address these items to the extent possible given limited data and information. Probabilistic assessment methods will allow sensitivity testing of exposure estimates or behavioral variance in time.

**Comment Topic**: Are the Limitations and Uncertainties Associated with the Scenarios Discussed in Sufficient Detail And, If Not, What Additional Information Should Be Included?

**Agency Response**:

The SAP commented that the SOPs should consider the different sources of uncertainty associated with each component of the exposure assessment, including contamination estimates and estimates of how individuals will encounter contaminants via different routes, as well as an overall clearer understanding of the sources and magnitude of uncertainty. The Agency agrees and will attempt to better characterize uncertainties and distributions of data and assumptions as new data and information becomes available. In the next version of the SOPs, for example, the representativeness of the PHED residential handler scenarios will be described to better estimate any uncertainties regarding the data.

**Comment Topic**: Are the SOPs a Reasonable Approach for Conducting a First Tier, Screening Level Residential Exposure Assessment When Chemical/product Specific Data Are Unavailable?

**Agency Response**:

The SAP commented that the general approach was very reasonable and appropriate given the inadequacies of available data. In the absence of reliable data needed to further refine exposure estimates, the Agency's proposed reliance upon conservative default assumptions about levels of exposure appears to be justified. The panel also commented that the dominant limitation is the over- reliance of the approach on assessment of a single medium of contamination and exposure and that the Agency should quickly develop methods to account for exposure to mixtures of chemicals (acting via the same mechanism) across diverse environmental compartments. The Agency agrees with

the Panel and has other workgroups assigned to looking at common mechanistic and cumulative exposure and risk issues. The SOP Workgroup will be coordinating with those groups.

**Comment Topic**: Since the SOPs Are Intended as a Tier I High-end Approach, Is the Use of an Additional Tenfold Margin of Safety Appropriate?

**Agency Response**:

The SAP commented that it is difficult to judge given the unknown magnitude of the uncertainties and conservative nature of some assumptions, but went on to comment that it appears the Agency is already applying a safety factor within the default assumptions. The Panel also commented on what methodological assumptions should be made about combining estimates of exposure across scenarios and that data sufficiency alone does not obviate the need for default methodological assumptions. The Agency has an aggregate exposure workgroup developing a draft guidance document for public comment. The Agency also agrees that data sufficiency does not necessarily obviate the need for default assumptions. The SOP workgroup will be incorporating results from the Occupational/Residential Exposure Assessment Group projects under the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (e.g., standard reference values: body weight, surface areas, respiration rates, etc.), which will address standardization of some the default assumptions routinely used in exposure assessments.